



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 1, 2005

FILE 6671

Jeffrey G. Roberts
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Dear Mr. Roberts:

Your petition requesting the Food and Drug Administration to deny approval of Smith & Nephew's premarket approval application (PMA) for the Birmingham hip resurfacing system (P040033) based on the data currently submitted in support of the PMA, was received by this office on 10/31/2005. It was assigned docket number 2005P-0440/CP1 and it was filed on 10/31/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005P.0440

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